

101



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,213	11/27/2001	Tim Kievits	65959/7	4072

7590 05/19/2004

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EXAMINER
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CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/997,213

Applicant(s)

KIEVITS ET AL.

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 18-21 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 18-21 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/403,559.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/29/02

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1641

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I – claims 1-11, 18-21, and 31-36 has been noted. Applicant is correct indicating that claims 1-11 and 18-21, and 31-36 were the only claims pending and thus the restriction requirement was not necessary.

### ***Specification***

2. The disclosure is objected to because of the following informalities:
  - a.) The status of 09/843,929 listed on page 1 of the specification should be updated as being issued as U.S. Patent 6,635,493.

Appropriate correction is required.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11, 18-21, and 31-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,225,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '131 claims a device and kit with essentially the same limitations as the instantly claimed device and kit.

Patent '131 claims a device for performing an assay comprising a substrate having through-going channels. The channels open out on a surface and oriented essentially perpendicular to the surface for sample application. The channels in at least one area of the surface for sample application being provided with a first binding substance capable of binding to an analyte, wherein the substrate is an electrochemically manufactured metal oxide membrane and the first binding substance is within the through-going channels in the substrate. The first binding substance can be a nucleic acid probe, an antibody, an antigen, a receptor, a hapten, or a ligand for a receptor. The first binding substance is covalently bound to the substrate. The metal oxide membrane can be composed of aluminum oxide. A kit containing the device is also claimed. The kit also includes a detection means for determining the whether binding has occurred between the first binding substance and the analyte. The detection means comprises a second binding substance provided with a label. The label is capable of inducing a color reaction or capable of bio- or chemo- or photoluminescence.

Patent '131 differs from the instant invention in failing to teach a binding substance that is a portion of a HIV protein or HIV genome.

However, it would have been obvious to one of ordinary skill in the art to use a portion of a HIV protein or HIV genome in the device of patent '131 because the device of patent '131 generically recites using various types of proteins, such as antibodies, antigens, receptors, haptens, and ligands and nucleic acid probes in general. The choice of analyte to be detected in the device of patent '131 dictates the appropriate reagents to be used. Should the analyte to be detected require a portion of a HIV protein or HIV genome then one of ordinary skill in the art would have provided each reagent.

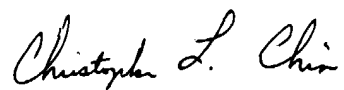
5. Claims 1, 4-6, 8-10, and 31-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,635,493. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '493 claims a method using a device with essentially the same limitations as the instantly claimed device.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin  
Primary Examiner  
Art Unit 1641

5/17/04